

Application No. 10/033,734  
Amendment "B" dated May 26, 2004  
Reply to Office Action mailed March 12, 2004

### REMARKS

Reconsideration and allowance for the above-identified application are now respectfully requested. Claims 1-43 are pending, wherein claims 1-3, 5-10, 12-17, 19-23, 29, 36 and 41 have been amended.

Applicants preliminarily wish to point out that a Revocation and Substitute Power of Attorney and Change of Attorney Docket Number were filed on January 24, 2003. A courtesy copy of the relevant documents filed at that time are enclosed for the Examiner. These documents indicate that the law firm of Workman Nydegger is currently the attorney of record and that the correct docket number is 7678.707. Please do not send any further correspondence to John P. O'Banion of O'Banion & Ritchey, LLP. Moreover, please use the correct attorney docket number when sending out any future correspondence.

#### **I. CLAIM REJECTIONS UNDER 35 U.S.C. § 102**

##### **A. Independent Claims 1, 8, 15 and 22**

The Office Action rejects claims 1, 8 and 15 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,941,256 to Guay et al., U.S. Patent No. 5,732,721 to Pelok, and U.S. Patent No. 5,906,834 to Tseng. In response, Applicants have amended claims 1, 8, and 15 in order to emphasize that which was already inherent, namely (1) that the dental floss "is colored prior to use" and (2) that removing the colored or coloring material from the dental floss while passing the dental floss between a user's teeth "indicate[s] which portion of said dental floss has been used". None of Guay et al., Pelok or Tseng teach or suggest a dental floss that is (1) "colored prior to use" and that (2) indicates which portion of the dental floss has been used through removal of a colored or coloring material coated on or impregnated in the dental floss.

##### **1. Guay et al.**

As discussed in the previous amendment, Guay et al. discloses dental floss to which microcapsules containing a pigment are attached. When the dental floss according to Guay et al. is passed between a user's teeth, the microcapsules are ruptured, thereby causing the pigment encapsulated therein to spill onto the dental floss so as to stain it and cause it to change color. Col. 1, lines 22-34; col. 3, lines 4-9; col. 3, lines 56-62; col. 4, lines 35-40. Prior to use, the dental floss of Guay et al. is not colored owing to the fact that the pigment is contained within

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microcapsules prior to use. *See id.* Staining of the dental floss disclosed in Guay et al. during use to show what portion of the floss has been used is the exact opposite of providing a dental floss that is colored prior to use and in which the colored or coloring material is removed during use to show what portion of the floss has been used. Moreover, the fact that a portion of the dye in Guay et al. may inherently diffuse into the user's mouth is irrelevant since such diffusion does not provide any indication as to what portion of the dental floss has been used. Staining of the floss is the only indication of use, for if the floss in Guay et al. is not stained with the dye it will not change color. Accordingly, Applicants submit that claims 1, 8, and 15 are neither anticipated by, nor obvious over, Guay et al.

## 2. *Pelok*

Pelok discloses a "dental floss for marking teeth" that is "impregnated or coated with a pressure sensitive material, such as a dye or chemically interactive material". Col. 1, lines 57-61. The only disclosed purpose of the "pressure sensitive material" is "for marking teeth". Col. 1, lines 7-9, 33, 35-36, 42 and 57-61; col. 2, lines 50-54. Marking the teeth helps a dentist in seating crowns and bridges. Col. 1, lines 11-20. The "articulating floss" of Pelok "provides the dentist with very accurate contacts. These contacts, usually within millimeters, give the dentist a much better clinical assessment of where and how much crown material to reduce, thereby leaving correct interproximal contacts. Col. 1, lines 23-28. The brief disclosure of Pelok neither teaches nor suggests coating or impregnating dental floss with a colored or coloring material so as to yield a dental floss that is colored prior to use and that changes color through removal of the colored or coloring material in order to indicate which portion of the dental floss has been used.

The mechanism by which the Pelok floss generates the "pressure sensitive" tooth staining material is through a chemical reaction involving chemically interactive substances that react during use:

One example of the pressure sensitive material comprises a plurality of dispersed cells each containing one of two chemically interactive substances. . . . The cells are ruptured in response to interproximal pressure caused by the distance between one tooth and an adjacent tooth being smaller than the diameter of the dental floss. The ruptured cells chemically interact and produce localized stained areas at precise locations where the

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interproximal spacing between the one tooth and the adjacent tooth is less than the diameter of the dental floss.

Col. 2, line 65 – col. 3, line 9. In another embodiment,

the pressure sensitive material contains two types of profusely dispersed minute liquid-containing cells. The two types of liquid-containing cells are kept chemically insulated from each other until the cells are ruptured by interproximal pressure when the dental floss is inserted between one tooth and an adjacent tooth due to the interproximal spacing between the teeth being smaller than the diameter of the dental floss.

Col. 3, lines 24-31. In yet another embodiment, "the pressure sensitive material contains chemically interactive materials, such as Ph [sic] indicators". Col. 3, lines 32-34. In the last embodiment, "the pressure sensitive material may comprise a plurality of micro-capsules dispersed in a carrier of a type well known in the art. . . . The mantle is relatively thin and pressure sensitive so as to be ruptured easily when pressure is applied." Col. 2, lines 39-46.

None of the examples of dental floss disclosed in Pelok include a dental floss that is (1) coated or impregnated with a colored or coloring so as to be colored prior to use and (2) that indicates which portion of the dental floss has been used through removal of the colored or coloring material. Accordingly, Applicants submit that claims 1, 8, and 15 are neither anticipated by, nor obvious over, Pelok.

### 3. *Tseng*

"The invention [disclosed in Tseng] relates to sustained-release matrices." Col. 1, line 11 (emphasis added). "The invention features sustained-release matrices that are particularly suited for use with toothbrushes." Col. 1, lines 53-54 (emphasis added). Such sustained-release matrices may include an anti-microbial agent or a colorant. Col. 1, lines 54-57. Examples of specific applications or devices that incorporate sustained-release matrices that contain an anti-microbial agent are disclosed at col. 3, lines 8-10 (toothbrush); col. 3, lines 11-18 (toothbrush, dental floss, or other dental instruments); col. 3, lines 19-30 (toothbrush); col. 4, lines 12-15 (toothbrush); and col. 4, line 32 – col. 8, line 35 (toothbrush). Examples of specific applications or devices that incorporate a sustained-release matrix that contains a colorant to denote wear is disclosed at col. 3, lines 31-64 (toothbrush) and col. 9, lines 9-60 (toothbrush).

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The only application or device disclosed in Tseng that incorporates a sustained-release matrix containing a wear-indicating colorant is a toothbrush. Tseng does not disclose any embodiments in which a dental floss has been coated or impregnated with a sustained-release matrix containing a wear-indicating colorant. Tseng only briefly mentions in passing coating dental floss with a sustained-release matrix, and then only with a matrix that includes an anti-microbial agent, not a colorant. *See* col. 3, lines 11-18; col. 11, lines 26-52.

Even if one were to construe Tseng as somehow teaching or suggesting coating dental floss with a sustained-release matrix that contains a colorant, such floss would not inherently "indicate which portion of [the] dental floss has been used" as required by each of claims 1, 8 and 15. That is because the sustained-release matrices of Tseng contain a water-insoluble polymer as a "support resin" that is designed to only slowly release the water soluble components incorporated therein over time. *See* col. 1, line 56-62; col. 2, lines 9-13 and 21-27; col. 4, lines 36-39; col. 10, lines 34-36. Because of this, the anti-microbial and/or colorant are slowly leached out of the sustained-release matrix over time. This is by design so that the toothbrush or other dental instrument is able to provide sustained-release of an anti-microbial agent during multiple uses and/or indicate wear by causing "the matrix to change color after repeated (at least 5) typical uses". Col. 3, lines 31-35 (emphasis added). Since it is well-known that dentists recommend brushing for 60 seconds or more, at least five "typical uses" of a toothbrush would require at least 5 minutes (or 300 seconds) before any color change occurs.

In the context of a hypothetical floss that one might argue is disclosed or suggested in Tseng, a user would have to rub this hypothetical floss between the user's teeth for at least 5 minutes (or 300 seconds) before any color change were to occur in order to indicate which portion of this purely hypothetical floss has been used. Since a person typically flosses for only a few seconds between each pair of adjacent teeth, the hypothetical floss arguably taught or suggested in Tseng would not be capable of indicating which part of the floss was used during normal or typical use. In fact, it would be absurd, if not unhealthy, for a person to continuously floss for 5 minutes or more between each pair of adjacent teeth just to find out what part of the floss has been used. It therefore follows that Tseng neither teaches nor suggests the manufacture of dental floss having the properties recited in claims 1, 8 and 15.

Claim 22 has been amended in order to claim a process in which dental floss is treated with a composition "consisting essentially of" the recited components and then dried. Support

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for drying is set forth at page 9, line 3 of the application. Use of the transition phrase "consisting essentially of" means that the claim is limited to dental floss manufactured using the specific components recited in claim 22, as well as any unrecited components that do not fundamentally alter the properties of the composition recited in claim 22. The composition recited in claim 22 does not include a substantial quantity of a water-insoluble polymer. As a result, the dental floss manufactured according to claim 22 does not meet the definition of a "sustained-release matrix" according to Tseng. Because the use of a substantial quantity of a water-insoluble polymer as a binder resin is a central feature of the invention disclosed in Tseng, it would be contrary to Tseng to manufacture a dental floss using a composition having the properties of the composition recited in claim 22. In view of the foregoing, Applicants submit that claim 22 as amended is neither anticipated by, nor obvious over, Tseng.

**B. Claims 6, 13, 20, 36 and 38**

The Office Action rejects claims 6, 13, 20, 36 and 38 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,357,989 to Gathani. The alleged basis for this rejection is that "Gathani discloses a dental floss that is coated with a color changing pH indicator. . . [that] changes color to specifically identify cariogenic bacteria in dental plaque". In response, independent claims 6, 13, 20 and 36 have been amended to claim a dental floss in which the disease indicating agent is "characterized by at least one of the following:

- (i) being sensitive to enzyme presence;
- (ii) being a fluoroscopic material;
- (iii) being an oral cancer detecting agent; or
- (iv) being a diabetes detecting agent."

Support for this limitation is found in the application at page 7, lines 1-13. Gathani neither teaches nor suggests that the pH indicators disclosed therein are characterized by any of properties (i)-(iv) recited in claims 6, 13, 20 and 36 as currently amended. Instead, they only change color in response to changes in pH. In contrast, none of properties (i) - (iv) are limited to measuring pH. For this reason, Applicants submit that claims 6, 13, 20 and 36 are neither anticipated by, nor obvious over, Gathani. Claim 38 depends from claim 36 and is likewise patentable.

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## II. REJECTIONS UNDER 35 § 103

### A. Claims 23-26

The Office Action rejects claims 23-26 under 35 U.S.C. § 103(a) as being obvious over Tseng or, alternatively, over Pelok. In response, claim 23 has been amended to claim a dental floss assembly comprising a dental floss that includes

a colored or color-changing material coating or impregnated within said dental floss that causes said dental floss to change color when said dental floss is passed between the teeth of a user in order to indicate which portion of said dental floss has been used, but which does not remain on the teeth

(Underlined text was added). Support for a colored or color-changing material that does not remain on the teeth is found in the application at page 6, lines 7-9. The practical advantage of this property is that use of a color-changing floss according to claim 23 does not stain the teeth, which could be embarrassing to the user if the user were to inadvertently stain his or her teeth and then go out into public. Good dental hygiene does not typically involve staining one's teeth.

As discussed above, Pelok discloses a dental floss that is specifically designed for "marking teeth". Because this tooth-marking feature is critical to the invention of Pelok, it would be contrary to Pelok to manufacture a dental floss assembly comprising a dental floss that includes a colored or color-changing material that "does not remain on the teeth". For at least this reason, Applicants submit that claim 23 as amended is neither taught nor suggested by Pelok.

As discussed above, Tseng discloses a sustained-release composition that, if it contains a color-changing material at all, only changes color after "at least 5 typical uses" of a toothbrush (i.e., after 5 minutes or 300 seconds). As such, Tseng neither teaches nor suggests a dental floss assembly that comprises dental floss that "change[s] color when said dental floss is passed between the teeth of a user in order to indicate which portion of said dental floss has been used". Thus, for the reasons given above with respect to claims 1, 8 and 15, Tseng likewise does not teach or suggest the dental floss assembly recited in claim 23 as now amended.

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**B. Claims 2, 3, 9, 10, 16 and 17**

The Office Action rejects claims 2, 3, 9, 10, 16 and 17 under 35 U.S.C. § 103(a) as being obvious over Pelok. In response, claims 2, 3, 9, 10, 16 and 17 have been amended to specify that the color-changing material or indicator dye do not remain on a user's teeth after use of the dental floss. In contrast, the only purpose of the dental floss of Pelok is to "mark" or "stain" the user's teeth. It would therefore be entirely contrary to Pelok to manufacture or use a dental floss that included a color-changing material or indicator dye that does not remain on the user's teeth.

**C. Claims 37, 39, 42 and 43**

The Office Action rejects claims 37 and 39 under 35 U.S.C. § 103(a) as being obvious over Gathani on the grounds that the specific disease indicating agents recited in claims 37 and 39 would have been obvious in light of the pH indicator of Gathani used to detect bacteria and plaque. However, the Office Action points to no teaching or suggestion in Gathani or anywhere in art that would have motivated one of skill in the art to substitute the pH indicators of Gathani with the cancer indicating agent of claim 37 or the fluoroscopic material recited in claim 39. Without a proper showing of motivation provided in the art, the rejection of claims 37 and 39 cannot stand. Moreover, detecting cancer or plaque using a fluoroscopic material is performed entirely independent of pH. Because it is critical for the floss in Gathani to change color within a specific acidic pH range (as argued in the previous Amendment) it would be contrary to Gathani to provide a dental floss that did not change color in response to detecting an acidic pH.

Claims 42 and 43 depend from claim 36, which is patentable for the reasons set forth above.

**D. Claims 7, 14, 21 and 29-35**

The Office Action rejects claims 7, 14, 21 and 29-35 under 35 U.S.C. § 103(a) as being obvious over Kent et al. In response, independent claims 7, 14, 21 and 29 have been amended to recite that the medicament is mixed within, or applied using, a composition comprising water, ethanol, and a water soluble polymer. Support for this limitation is found in the Example at page 8, which discloses a composition as recited in claims 7, 14, 21 and 29 that also includes one or more medicaments (*i.e.*, CHG, CHA and NaF). An advantage of this formulation is that "[q]uite

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surprisingly, this formulation increases the strength of the dental floss, decreases the ability to fray, slides easier between tight contacts of the dentition, and creates a lubricating effect." Application, page 6, lines 17-19. Kent et al. neither teaches nor suggests applying a medicament to dental floss using the specific formulation recited in claims 7, 14, 21 and 29 as amended.

### III. REJECTIONS UNDER 35 U.S.C. § 112

The Office Action rejects claims 5, 12 and 19 under 35 U.S.C. § 112, § 1, as failing to comply with the written description requirement, particularly with respect to the use of the term "only". In response, Applicants have deleted this term from claims 5, 12 and 19.

The Office Action rejects claims 4, 5, 11, 12, 18, 19 and 40 under 35 U.S.C. § 112, § 1, as failing to comply with the enablement requirement, particularly with respect to claiming color-changing materials that change color upon reaction with enzymes in the mouth. The same rejection was made with respect to claims 23-28. In response, Applicants note that this limitation was contained in the originally filed claims. As such, those claims provided generic disclosure of such materials as of the filing date. In light of this, one of ordinary skill in the art, through routine testing, could, given the present disclosure, select from among commonly-known materials that are known to change color when exposed or reacted with enzymes.

Moreover, the application at page 7, lines 1-15 provides examples of disease-indicating materials that are known to identify the existence of a particular disease in a person's mouth as a result of the presence of enzymes when such conditions exist. In connection with these examples, the application specifically mentions a color-changing function as a result of the presence of such enzymes. Page 7, lines 12-13. In view of the foregoing, Applicants submit that claims 4, 5, 11, 12, 18, 19 and 40, as well as claims 23-28, are adequately enabled by the originally filed application.

Claim 41 has been amended to overcome the rejection under 35 U.S.C. § 112, § 2 by eliminating a recited disease-identifying method of use and replacing it with a disease-indicating property of the disease-indicating agent.

Because claims 4, 5, 11, 12, 18, 19, 40 and 41 were not rejected over any prior art, they are believed to be in allowable form.



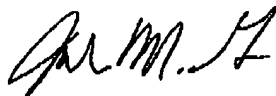
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#### IV. CONCLUSION

In view of the foregoing, Applicants believe that the present Application is in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or which may be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 26<sup>th</sup> day of May 2004.

Respectfully submitted,



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